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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,612	01/05/2004	T. Erik Mirkov	017575.0774 (TAMUS 1910)	2393
5073	7590	05/10/2005	EXAMINER	
BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980			MCELWAIN, ELIZABETH F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/751,612

Applicant(s)

MIRKOV ET AL.

Examiner

Maria Teresa Samson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2-33 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05-January 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01-February 2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-33 are pending.

Specification

(A.) The specification on page 31 line 17, the word "identify" is misspelled.

(B.) The drawings are objected to because figure 10 is too dark and no details can be made out.

(C.) The drawings are objected to because figures 5, 7-9, 11, 13 and 14 cannot have a brief description on the legends of the figures.

(D.) The drawings are objected to because each page of the figure 9 must be given a number. Thus the first page of figure 6 should be figure 9A, the second figure 9B, etc.

Claim Objections

Claim 5 are objected to because of the following informalities:

In claim 5, one of the "in a " should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(A.) Claims 2-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to a stem-regulated promoter having a sequence at least 65% homologous to SEQ ID NO: 1, an isolated nucleic acid comprising an OMT promoter and an exogenous nucleic acid, wherein the OMT promoter is operable to drive stem-regulated expression of the exogenous nucleic acid in the absence or presence of a defense-inducing agent, an expression vector comprising the OMT promoter, an exogenous nucleic acid and 3' termination sequence, a plant cell comprising an expression vector wherein the exogenous nucleic acid alters carbon metabolism when expressed or encodes an insecticide effective against an insect, plant comprising the expression vector and expression of the exogenous nucleic acid is stem-regulated or is upregulated by the presence of a defense-inducing agent and expression of exogenous nucleic acid alters carbon metabolism in plant or encodes an insecticide against an insect, a method of directing stem-regulated expression of a nucleic acid in a plant in the absence or presence of a defense-inducing agent.

Applicant does not describe a stem-regulated promoter having a sequence at least 65% homologous to SEQ ID NO: 1, an isolated nucleic acid comprising an OMT promoter and an exogenous nucleic acid, wherein the OMT promoter is operable to drive stem-regulated expression of the exogenous nucleic acid in the absence or presence of a defense-inducing agent, an expression vector comprising the OMT promoter, an exogenous nucleic acid and 3' termination sequence, a plant cell comprising an expression vector wherein the exogenous nucleic acid alters carbon metabolism when expressed or encodes an insecticide effective against an insect, plant comprising the expression vector and expression of the exogenous nucleic acid is stem-regulated or is upregulated by the presence of a defense-inducing agent and expression of exogenous nucleic acid alters carbon metabolism in plant or encodes an insecticide against an

insect, a method of directing stem-regulated expression of a nucleic acid in a plant in the absence or presence of a defense-inducing agent.

Furthermore, there is no functional description of a stem-regulated promoter having a sequence at least 65% homologous to SEQ ID NO: 1 or a nucleic acid molecule on promoters of any OMT gene that can drive stem-regulation expression in the absence or presence of a defense-inducing agent. Applicant does not describe the sufficient structural elements of SEQ ID NO: 1 that are required for function and that these structural elements are also present in nucleic acid molecules that is at least 65% homologous to SEQ ID NO: 1. The Applicant does not describe the sufficient structural elements of a representative number of nucleic acids that is at least 65% homologous to SEQ ID NO: 1 and has stem-regulated promoter activity. The applicant does not describe the sufficient structural elements of the nucleic acid molecule on promoters of any OMT gene that are required for function and does not describe the sufficient structural elements of a representative number of nucleic acid molecule on promoters of any OMT gene that drives stem-regulated expression of the exogenous nucleic acid in the absence or presence of a defense-inducing agent.

Claims 2-33 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2-33 are drawn to a stem-regulated promoter having a sequence at least 65% homologous to SEQ ID NO: 1 and OMT promoter that can drive stem-regulated expression of the exogenous nucleic acid in the absence

or presence of a defense-inducing agent and that is claimed solely by function and without any structural limitations.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, SEQ ID NO: 1 has been set forth, and shown to have stem specific promoter activity. This DNA sequence is only described according to the functional characteristics of the promoter activity, for example; no structural relationship is described or used in the claims. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. Therefore, the claims are not adequately described.

Hence, the specification fails to provide an adequate written description of the genus claimed.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed nucleic acids, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

(B.) Claims 2-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the OMT1 promoter of SEQ ID NO: 1 and sugarcane and rice plants comprising the vector comprising the OMT1 of SEQ ID NO: 1, does not reasonably provide enablement for any plant transformed with a promoter of any OMT gene from any source operably linked to an exogenous nucleic acid that when express in the absence or presence of a defense-inducing agent alters either carbon metabolism or encodes an insecticide that is effective against an insect. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a stem-regulated promoter having a sequence at least 65% homologous to SEQ ID NO: 1, an isolated nucleic acid comprising an OMT promoter and an exogenous nucleic acid, wherein the OMT promoter is operable to drive stem-regulated expression of the exogenous nucleic acid in the absence or presence of a defense-inducing agent, an expression vector comprising the OMT promoter, an exogenous nucleic acid and 3' termination sequence, a plant cell comprising an expression vector wherein the exogenous nucleic acid alters carbon metabolism when expressed or encodes an insecticide effective against an insect, plant comprising the expression vector and expression of the exogenous nucleic acid is stem-regulated or is upregulated by the presence of a defense-inducing agent and expression of

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exogenous nucleic acid alters carbon metabolism in plant or encodes an insecticide against an insect, a method of directing stem-regulated expression of a nucleic acid in a plant in the absence or presence of a defense-inducing agent.

Applicant's teachings only provide guidance for vector construction of either the OMT1 promoter (SEQ ID NO: 1) or the OMT2 promoter into the pUC19 GUS reporter and stable expression of GUS under the control of the OMT promoter is achieved in sugarcane and expression is stem-specific (pages 39-, example 4); a rice vector construction and stable expression of GUS under the control of either the OMT1 (SEQ ID NO: 1) promoter or OMT2 promoter is achieved in rice and expression is in the stem vascular bundles (page 41, example 4).

The specification does not teach making DNA molecules that is at least 65% homologous to SEQ ID NO: 1 that has stem-regulated promoter activity or any DNA molecule on the promoters of any OMT gene which can be used to drive stem-regulated expression of the exogenous nucleic acid in the absence or presence of a defense-inducing agent. The specification does not exemplify transforming a plant with a DNA molecule on the promoters of any OMT gene which can be used to drive stem-regulated expression of the exogenous nucleic acid in the absence or presence of a defense-inducing agent or a DNA molecule that is at least 65% homologous to SEQ ID NO: 1 that has stem-regulated promoter activity with the full scope of the claims and does not teach to make them.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the

invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

In addition, the specification does not provide any guidance with regard to the identity and location of key nucleotides and regulatory regions required for stem-specific promoter function and if these key nucleotides and regulatory regions are also required for induction by a defense-inducing agent and the claims are drawn to a multitude of sequences.

The presence of a conserved motif within promoters of genes that are expressed in the same tissue or are induced by the same inducing agent is not necessarily responsible for directing the expression of genes in a tissue or for directing the expression of genes in the presence of an inducing agent. For example, Ulmasov et al demonstrate that although ocs-like element, which has been identified as a putative auxin response element on promoters of auxin inducible genes based on conservation of similar sequence elements found in a variety of genes induced by auxin, does not appear to be specific for auxin (The Plant Cell, 7:1611-1623, 1995, page 1611, column 1, first paragraph). In addition, auxin-responsive genes that are specifically induced by auxins do not appear to contain the ocs-like element. Furthermore, the GCC box is an ethylene-responsive element and has been found in the promoters of ethylene-inducible PR family of genes but not found in the promoters of ethylene-responsive genes that are involved in ripening and senescence (Hiroyuki et al., Plant Science 155: 85-1000, 2000, page 94, column 2, second paragraph). Furthermore, comparison of the promoter sequence of GS with other promoter sequences deposited in the eukaryotic promoter database revealed very little homology with the regulatory regions of other genes, including plant GS genes (Muhitch et al., Plant Science, 163: 865-872, 2002, page 868, column 2, second paragraph). Thus, conserved motifs found within

several promoters may not be responsible for directing gene expression and sequence similarities may not exist between promoters. Thus, nucleotide sequences on promoters of other OMT genes or nucleic acid molecule that is at least 65% homologous to SEQ ID NO: 1 may not exist and if such nucleic acid molecule does exist, will it have the same promoter activity as SEQ ID NO: 1?

Mutation of promoter sequences is unpredictable. Donald et al (1990, EMBO J. 9:1717-1726) in a mutational analysis of the *Arabidopsis rbcS-1A* promoter found that the effect of a particular mutation was dependent on promoter fragment length (paragraph spanning pg 1723-1724).

Additionally, extensive further experimentation would be required to isolate and clone other nucleotide sequence that is at least 65% homologous to SEQ ID NO:1 and to determine whether the sequences have stem-regulated promoter activity or a nucleotide sequence on promoters of any OMT gene that drive stem-regulated expression in the absence or presence of a defense-inducing agent. The specification does not teach where to find such promoters and does not teach how to make them.

Moreover, the specification does not teach how to use the method of directing stem-regulated expression of a nucleic acid in a plant using a nucleotide sequence on promoters of any OMT gene operably linked to a gene and expression of the gene is stem-regulated in the absence or presence of an inducing agent. Furthermore, there is no guidance with regard to how one would analyze transformed plants for improved resistance to insects or how one would analyze transformed plants for alters carbon metabolism in the plant cell.

Thus, given the limited teachings and guidance by Applicant, the nature of the art and the unpredictability of the art, undue trial and error experimentation would have been required by

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one of skill in the art at the time of Applicant's invention to screen through a myriad of nucleotide sequence that is at least 65% homologous to SEQ ID NO: 1 to find those that are stem-specific promoters or a nucleotide sequence on the promoters of any OMT gene to find those that drive stem-regulated expression in the absence or presence of a defense-inducing agent.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claim is included in all rejections.

(A.) Claims 19 and 27 are indefinite in their recitation of "expression nucleic acid in an expression vector" in line 2. It is not clear if the OMT promoter is part of the expression vector as well as the 3' termination sequence. It is suggested that the expression vector comprises, in a 5' to 3' direction an OMT promoter, an exogenous nucleic acid and a 3' termination sequence.

(B.) Claims 3-33 is indefinite in its recitation of the abbreviation "OMT". The term should be defined with in the claims.

Claims 1-33 are free of prior art

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Conclusion

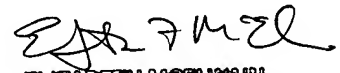
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Teresa Samson whose telephone number is 571-272-3110. The examiner can normally be reached on 7:00-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Maria Teresa Samson, Ph.D
April 5, 2005


ELIZABETH MCELWAIN
PRIMARY EXAMINER